IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant:	RAUL, *et al.*		
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Examiner:	Orwig, Kevin S		
Docket No.:	DC5078 PCT1		
Customer No.:	00137		
For:	Method of Making Silicone Pressure Sensitive Adhesives for Delivering Hydrophilic Drugs		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT UNDER 37 C.F.R. §1.132

Sir:

I, Gerald K. Schalau, II, being duly sworn, say that:

1. I received a Bachelor of Science degree in biology from Eastern Nazarene College in Quincy, MA in 1990 and MBA in from Northwood University, Midland MI in 2005 .

2. I have been employed by the Dow Corning Corporation at Midland, Michigan since 1998, during which time I have been engaged in research and development activities in the fields of adhesives for transdermal drug delivery and wound care applications. I am a co-inventor of 8 U.S. patents/ patent applications.

3. I am familiar with the above identified patent application.

4. Under my supervision, the following experiments were performed:

4.1a: 10 wt% niacinamide was added to PSA/polyether wax formulation according to U.S. Patent No. 5,607,721. Niacinamide is a hydrophilic drug that is provided as a micronized powder. Samples were prepare by melting the polyether wax and then adding in the solvated PSA and niacinamide and mixing for 90 sec at a 100 setting on a Variac and malt-type mixer. The resulting mixture was immediately applied to a release liner to devolatize the solvent at 22°C.

4.1b: Using the same components as in 1a, a sample was prepared by melting the wax and adding the niacinamide to the wax. This mixture was formed into a paste using a mortar and pestle. This paste was then added to the solvated PSA and mixed for 90 sec at a 100 setting on a Variac and malt-type mixer. The resulting mixture was immediately applied to a release liner to devolatize the solvent at 22°C.

5. Figure 1 is a micrograph of sample 4.1a and Figure 2 is a micrograph of sample 4.1b. As can be seen in Figure 1, the number of drug particles and size of niacinamide particle/crystal is much larger than 100 μm. As can be seen in Figure 2 the size of the particle is approximately 100 μm. Thus, by adding the niacinamide to the polyether wax first, an improvement in particle size in the resulting PSA results.

Figure 1 (Magnification 200X)

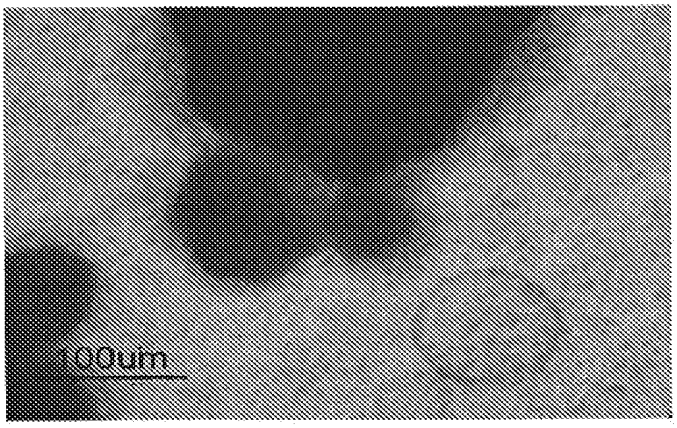
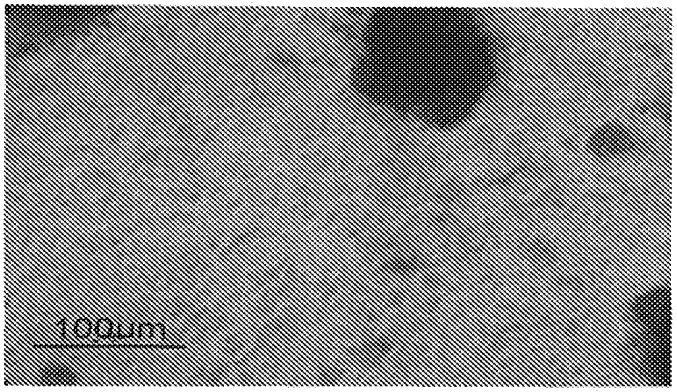
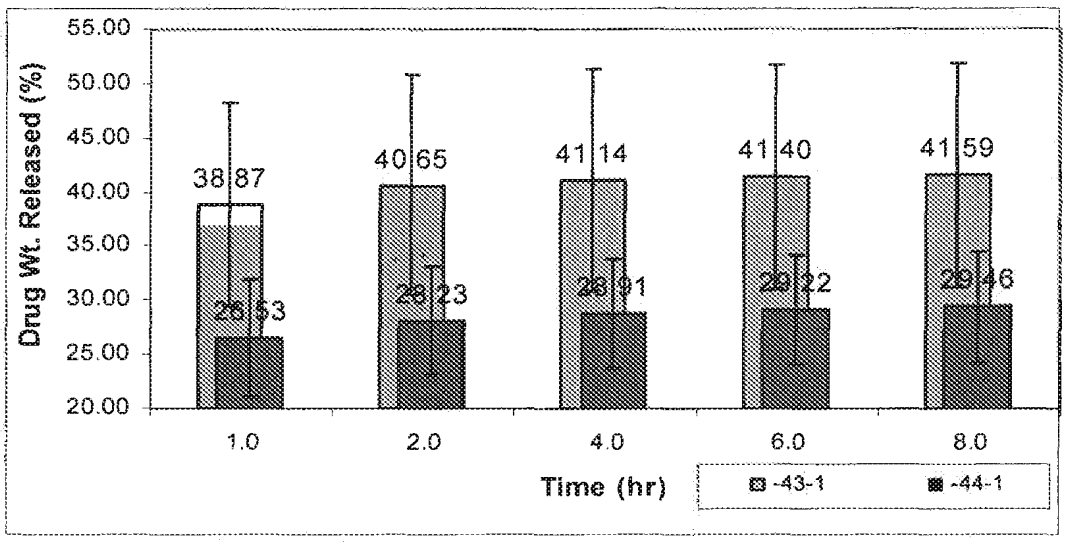


Figure 2 (Magnification 200X)



6. Three 1.9 cm diameter discs were cut from the laminates prepared above. Drug flux from these laminates was accomplished using a Franz cell with a 0.9% sodium chloride solution in water at the receptor fluid. Aliquots were tested for drug concentration via HPLC at 1, 2, 3, 4, 6 and 8 hour with total replacement of receptor fluid at each interval. As can be seen in Figure 3, sample 4.1a had a higher percentage of drug release and had a higher relative standard deviation (RSD). Sample 4.1a had a RSD of 25% while sample 4.1b had a RSD of 18%.

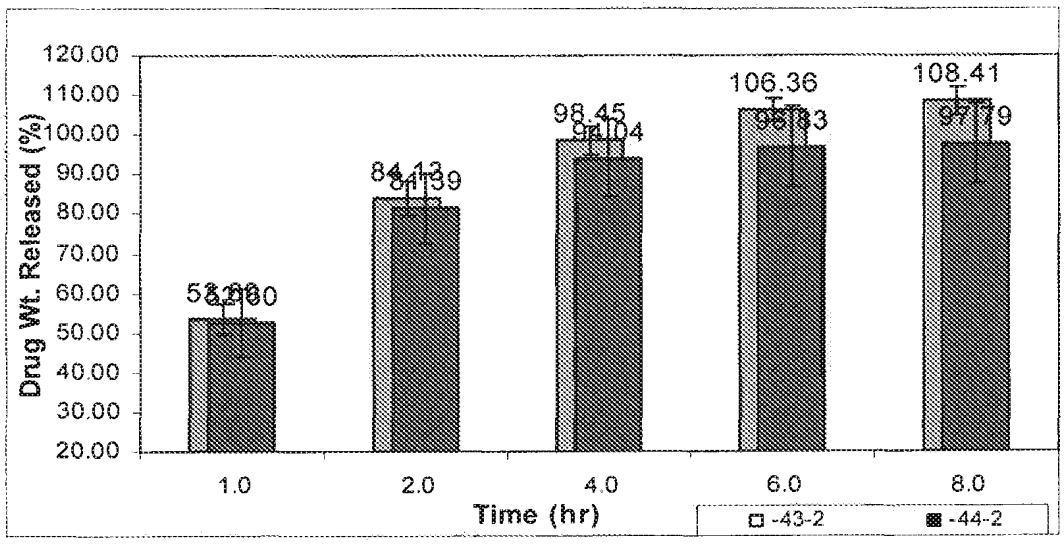
Figure 3



7. Samples 7.1a and 7.1b were prepared as described in paragraph 4 above except that liocaine was used as the drug. Lidocaine is a less hydrophilic crystalline drug than niacinamide. Figure 4 is a micrograph of sample 7.1a and Figure 5 is a micrograph of sample 7.1b. As can be seen in Figure 4, the size of lidocaine crystal is much greater than 100 μm. As can be seen in Figure 5 there is an absence of crystalline particles of lidocaine. Thus, by adding the lidocaine to the polyether wax first, an improvement in particle size in the resulting PSA results.

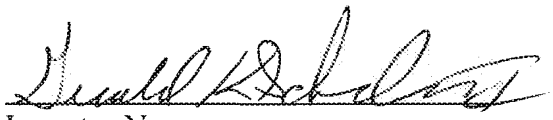
8. Three 1.9 cm diameter discs were cut from the laminates prepared above. Drug flux from these laminates was accomplished using a Franz cell with a 0.9% sodium chloride solution in water at the receptor fluid. Aliquots were tested for drug concentration via HPLC at 1, 2, 3, 4, 6 and 8 hour with total replacement of receptor fluid at each interval. As can be seen in Figure 6, the samples were comparable in drug release and relative standard deviations.

Figure 6



9. Based on the above experiments it is my opinion that by adding the drug to the silicone polyether prior to mixing with the PSA that there are unexpected benefits in compatibility of the drug in the matrix (as evidenced by particles in the matrix) and that depending on the hydrophilic nature of the drug the release from the matrix is more consistent.

I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I also declare that, at the time these statements were made, I knew that willful false statements and the like are punishable by a fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that those willful false statements may jeopardize the validity of the application, or any patent issuing from it.



Inventor Name

Date: 08 MAY 2009